

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Tadashi GOINO

Confirmation No: 8173

Application No.: 10/589,357

Group No.: 1655

Filed: October 2, 2006

Examiner: Randall O. Winston

For: PHYSIOLOGICALLY ACTIVE COMPOSITION AND PREPARING
METHOD THEREOF

Commissioner for Patents

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SUBMISSION ACCOMPANYING REQUEST FOR CONTINUED EXAMINATION


This submission accompanies a request for continued examination and follows the final rejection of May 28, 2010. Please charge deposit account 12-0425 the sum of \$ 555 for a three months extension of term for response and \$405 for the filing of the Request for Continued Examination. .

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10*

I hereby certify that, on the date shown below, this correspondence is being:

TRANSMISSION

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John Richards

(type or print name of person certifying)

Date: November 26, 2010

The listing of claims presented below replaces all prior versions and listing of claims in the application.

Listing of claims:

1. (Previously presented) A physiologically active composition containing a combination of : an extract component from a fungus *Ganoderma lucidum*, a fungus *Coriolus Versicolor*, and a fungus *Phellinus lineus*; and an extract component from a root of *Panax japonicus* C. A. Mayer, and wherein the oxidation-reduction potential of an aqueous solution of the composition is not less than 330 mV
2. (Canceled)
3. (Withdrawn) The composition according to Claim 1, wherein the *Agaricus* fungus is *Agaricus blazei* Murill.
4. (Canceled)
5. (canceled)
6. (Canceled)
7. (Previously presented) The composition according to Claim 1, wherein the oxidation-reduction potential of an aqueous solution of the composition is not more than 1230 mV.
8. (Original) The composition according to Claim 7, wherein the oxidation-reduction potential of an aqueous solution of the composition is not more than 330 mV
9. (Previously presented) The composition according to Claim 1, wherein pH of an aqueous solution of the composition is not less than 4.5 and not more than 6.5.
10. (Previously presented) The composition according to Claim 1, wherein the extract composition are respectively extract components with hot water.
11. (Previously presented) A drug formulation which is mixed when used and is provided with a first drug comprising an extract from a fungus *Ganoderma lucidum* a fungus *Coriolus*

Versicolor,, and a fungus *Phellinus lineus*; and an extract component from a root of *Panax japonicus* C. A. Mayer, and wherein the oxidation-reduction potential of an aqueous solution of the composition is not less than 330 mV, and a second drug comprising an extract component from a root of a plant belonging to Araliaceae .

12. (Original) A preparing method of a physiologically active composition, said method comprising the steps of;

extracting with hot water anyone of a carpophore, a mycelium and a culture of a fungus belonging to Basidiomycetes Aphyllophorales *Ganoderma Ganodermaceae* and/or a fungus belonging to Basidiomycetes Polyporaceae *Coriolus*;

extracting with hot water anyone of a carpophore, a mycelium and a culture of a fungus belonging to Basidiomycetes Agaricales Agaricaceae *Agaricus* and/or a fungus belonging to Basidiomycetes Agaricales Hymenochaetaceae *Phellinus*;

extracting a root of a plant belonging to Araliaceae with hot water; and

mixing the extract components with the hot water obtained in the extracting steps.

13. (Original) A preparing method of the physiologically active composition, said method comprising the steps of:

obtaining a hot water extract from anyone of a carpophore, a mycelium and a culture of a fungus belonging to Basidiomycetes Aphyllophorales *Ganoderma Ganodermaceae* and/or a fungus belonging to Basidiomycetes Polyporaceae *Corio Ius*, a hot water extract from anyone of a carpophore, a mycelium and a culture of a fungus belonging to Basidiomycetes Agaricales Agaricaceae *Agaricus* and/or a fungus belonging to Basidiomycetes Agaricales Hymenochaetaceae *Phellinus*, and a hot water extract from a root of a plant belonging to Araliaceae separately or from the same extraction system with respect to at least more than two kinds of the hot water extracts, so as to prepare a composition comprising the hot water extract component from anyone of a carpophore, a mycelium and a culture of a fungus belonging to Basidiomycetes Aphyllophorales *Ganoderma Ganodermaceae* and/or a fungus belonging to Basidiomycetes Polyporaceae *Coriolus*, the hot water extract component from anyone of a carpophore, a mycelium and a culture of a fungus belonging to Basidiomycetes Agaricales Agaricaceae *Agaricus* and/or a fungus belonging to Basidiomycetes Agaricales Hymenochaetaceae *Phellinus* and the hot water extract component from a root of a plant belonging to Araliaceae.

14 (new) A physiologically active composition according to claim 1 wherein *Ganoderma lucidum*, *Coriolus Versicolor* *Phellinus linteus* and *Panax japonicus* C. A. Mayer are present in a ratio of 1:1:1:1 by weight.

REMARKS

All claims are rejected over a combination of Kouge et al US 20040029955, newly-cited Huffstuler US 5466455, Son KR 200108366 and its Derwent abstract and Yuan 20020136785.

In response to the previous action the applicant pointed out that the Goino reference then cited did not qualify as prior art to be cited against this application. The examiner replaces this by Huffstuler which does qualify as prior art, but teaches nothing that might make the claimed invention obvious.

Huffstuler's teaching is that one can apply his new, and very broadly described, technique to extract active ingredients from virtually any plant material that has ever been used in East Asian traditional medicine. Huffstuler does teach that extracts can be obtained from freshly harvested plant tissue including flowers, seeds, leaves, anthers, callus cultures, buds, blossoms, pollen, petioles, stems and rhizomes, and roots of any one of over 90 plant species. *P. japonicus* is listed among these 90 species. There is no mention of the C.A. Mayer variety. The extraction method taught for all of the *Panax* species is to extract with water, a C_{1-10} alcohol, a C_1 - C_3 ketone, a C_1 - C_4 acetate, a C_1 - C_4 ether, a C_1 - C_3 hydrocarbon, acetonitrile, toluene, and solutions/dispersions thereof with liquid and/or vapor phases. The temperature can be from 20 - 400°K (i.e. -253 to + 127°C). The product may be used in a wide range of formulations. Bioactive compounds from *Panax* extracts are said to be useful in treating tumors, anemia, myocardial circulation, cerebral ischemia as well as preventing free-radical damage and platelet aggregation. The introductory portion of the specification notes traditional use of ethanol extracts of dried *Panax* roots but states that there has been no prior teaching to use freshly harvested *Panax* material. There is no working example of extraction from a *Panax* source. The examiner points to claims 5 and 6 as providing teaching that may be relevant to the present invention. Claim 5, however is dependent on claim 2 and relates to *Taxus* rather than *Panax* extracts. Claim 6 does relate to *Panax* sources, including *P. japonicus*. The technique involves treating plants with bacteria prior to harvesting, extraction involves use of a mixture of polar and non-polar solvents using his claimed technique.

It seems therefore that the examiner is reading too much into this document. It makes no mention of the particular variety of *P. Japonicus* specified in the present claims. It makes no reference to the product as an aqueous solution. Both of which are essential features of all claims. It makes no mention of using a hot water extract as required by the method claims..

As pointed out in response to the previous action, these features are missing from the other cited art as well. Although ginseng root has been used in Chinese traditional medicine for many years (see Yuan paragraph 18), neither Son nor Yuan teaches use of the root of *Panax japonicus* for any purpose. Yuan teaches the use of berries of *Panax ginseng* or *Panax quinquefolius*. Son simply refers to the use of an unsaturated fatty acid extract of sesame and an alkaline extract of ginseng. Neither of these therefore gives even the slightest hint that an extract from the root of *Panax japonicus* C. A. Mayer should be used. As noted above, Hufstuler does mention use of roots as well as almost every other part of a plant. However, this teaching is so broad both having regard to the nature of the plants and the parts of the plants to be considered that it gives no useful guidance. What Hufstuler is concerned about is using fresh produce and his extraction technique, which is not the same as the present applicant's, not the selection of particular parts of particular varieties of particular species of a plant to secure a particular result.

The examiner has made no response to the arguments we put forward previously that none of the art cited previously relates to the plant materials from *Panax japonicus* C.A. Mayer, although the examiner now apparently relies upon the newly cited Hufstuler to show use of an extract from *Panax japonicus* root. As noted above, the Hufstuler reference cannot support the weight of this reliance.

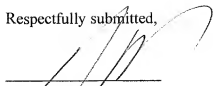
Even when read together the "plant material" references do not point to a hot water extract from *P. japonicus* C.A. Mayer root. The examiner has therefore not identified a plant extract material in the prior art that might be combined with Kouge's fungal material. It is therefore submitted that the invention as claimed is not obvious over the prior art.

It is therefore submitted that the requirements of 35 USC 103 have been met.

In view of the foregoing, it is submitted that this application is in order for allowance and an

early action to this end is respectfully solicited.

Respectfully submitted,

A handwritten signature in dark ink, appearing to be 'JR' with a large, sweeping flourish extending to the right.

JOHN RICHARDS

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